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EXAMINER	
KOLKER, DANIEL E	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,423	ROULEAU ET AL.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/18/07, 3/28/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,17,20,23-25 and 30-38* is/are pending in the application.

4a) Of the above claim(s) *24,25 and 35-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,17,20,23 and 31* is/are rejected.

7)☒ Claim(s) *30,32-34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Sequence alignment (6 pgs)*.

DETAILED ACTION

1. The remarks and amendments filed 18 December 2007 and 28 March 2008 have been entered. Claims 14, 17, 20, 23 – 25, and 30 – 38 are pending.

Election/Restrictions

2. Newly submitted claims 24 – 25 and 35 – 38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally-presented claims were drawn to products (nucleic acids, vectors, and cells harboring the nucleic acids). Claims 24 - 25 as amended and new claims 35 - 38 are drawn to methods of using nucleic acids.

The inventions set forth as claims 14, 17, 20, 23, and 30 – 34 on the one hand and claims 24 – 25 and 35 – 38 on the other hand are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of claim 24 can be performed with other nucleic acid samples, as genes other than SCN1A are known to be mutated in epileptic patients. See for example Singh et al., cited as reference C64 on IDS filed 10 November 2003.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 24 – 25 and 35 – 38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 14, 17, 20, 23, and 30 – 34 are under examination.

Withdrawn Rejections and Objections

4. The following rejections and objections set forth in the previous office action are withdrawn:

A. The rejection of record under 35 USC 112, first paragraph for lack of enablement commensurate in scope with the claims, is withdrawn in light of the amendments to the claims. The claims are now limited to nucleic acids which encode sodium channels (claim 14 parts (a) and (c)), or which are fully complementary to same (claim 14 part (b)) or which are useful as probes to detect same (newly added part (d) of claim 14). Search of the sequence databases

indicates that the specific sequences recited in claim 14 part (d) will be specific as probes for SCN1A sequences, as asserted by the specification (see for example specification, p. 11 line 20 – p. 12 line 28) and determining the presence of a polymorphism (specification p. 4 line 26 - p. 5 line 7).

B. The rejection under 35 USC 112, first paragraph, for lack of adequate written description is withdrawn in light of the amendments, arguments, and upon careful consideration of the newly-disseminated guidelines on interpretation of the written description requirement (available at http://www.uspto.gov/web/menu/written.pdf).

C. The rejection of claim 25 for recitation of new matter is now moot. Claim 25 is now drawn to a non-elected (method) invention.

New Rejections and Objections

Priority

5. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/167623, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The examiner is unable to find disclosure of the D188V mutation in SCN1A in the provisional application. While the D188V mutation is disclosed in the specification of parent application 09/718355 at p. 55 lines 3 - 25, the examiner is unable to find support for this limitation in the provisional application. This mutation is recited in claim 32. Therefore, for the purposes of applying prior art, the effective filing date of claims 14, 17, 20, 23, 30 - 31, and 33 – 34 is 26 November 1999, the date that provisional application 60/167623 was filed. The effective filing date of claim 32 is the date the 09/718355 application was filed, 24 November 2000. The examiner notes that provisional application 60/167623

discloses the Glu1238Asp and Ser1773Tyr mutations, recited in claims 33 - 34, at p. 39 lines 10 - 25. The specific sequences recited in claim 30 are found at p. 39 of the provisional application.

Should applicant disagree with the examiner's factual determination, applicant should provide evidence or point to evidence currently of record which indicates that the provisional application provides support for the limitations recited in claim 32. This could be accomplished, for example, by pointing to specific page and line numbers or to figures or sequences in the 60/167623 application.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14, 17, 20, 23, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda (1987. Journal of Receptor Research 7:467-497) in view of Wood (WO 97/01577, published 16 January 1997), Malo (1994. Cytogenet Cell Genet 67:178-186, cited as reference C45 on IDS filed 10 November 2003), and Current Protocols in Molecular Biology (1989 – 1996, pages 6.0.3 – 6.0.5, 6.1.1 – 6.1.4, 6.3.1 – 6.3.6, and 6.5.1 – 6.5.2).

Noda teaches a nucleic acid encoding rat sodium channel. The sequence from Noda encodes a protein that is 98.6% identical to the protein of SEQ ID NO:3; see enclosed sequence alignment. SEQ ID NO:3 is the human adult form of human sodium channel 1A (specification, p. 27, lines 16 – 17). Therefore the reference by Noda is on point to claim 31, drawn to a protein encoding SEQ ID NO:3, as well as parent claim 23. Since parent claim 23 recites one of the limitations of claim 14, namely nucleic acids at least 95% identical to SEQ ID NO:1, the

reference is on point to claim 14 as well. Noda teaches vectors and cells carrying the nucleic acids encoding this protein; see p. 469, which is relevant to claims 17 and 20. However Noda does not explicitly teach a nucleic acid encoding SEQ ID NO:3, as recited in claim 31 and encompassed by claims 14 and 23.

Wood teaches a number of screening methods with recombinant sodium channels, and teaches that they are useful for identifying new drugs. See p. 2 line 18 – p. 3 line 2, p. 3 line 30 – p. 4 line 2, and p. 38 line 3 – p. 39 line 17. Wood also teaches that when a sodium channel from one species is known, and the nucleic acid encoding the channel is in hand, one can screen a cDNA library made from a second species in order to obtain the nucleic acid encoding the same protein from the second species. Note that Wood indicates while certain examples discuss rat sequences, human sequences can also be used (p. 5 lines 18 - 31 for example). Wood also teaches alternative methods to identify human sodium channel sequences, by using PCR, and teaches how to confirm that the appropriate clone has been obtained with an *in vitro* assay (p. 28 line 18 – p. 32 line 2). However while Wood teaches these methods relating to sodium channels expressed in the periphery, the reference does not explicitly teach sodium channels encoded by nucleic acids identical to SEQ ID NO:3, as encompassed by claims 14, 23, and 31.

Malo teaches nucleic acids which are partial sequences of human sodium channel 1 alpha, also known as SCN1A. See in particular p. 179 second column ("Results"), Figure 2 on p. 181, p. 182 "Assignment of a human brain sodium channel 1α (SCN1A) gene", and Figure 3, appearing on p. 183, which shows the sequence of the isolated nucleic acid and encoded protein. Note that Figure 3 shows substantial identity between the human SCN1A sequence and that rat Scn1a (also called RBI) sequence at the amino acid and nucleic acid levels. While the human sequence is obviously only a partial sequence, at both the nucleic acid and amino acid levels, the high degree of homology between the identified human sequences and the rat sequence known in the prior art (Note that Figure 3 from Malo indicates that the rat sequence is that from Noda 1986; this is the same sequence used by Noda 1987, cited above; see also Noda 1987 p. 469 and 496) suggests to the artisan of ordinary skill that the full-length human sequence could be obtained. Malo teaches that the partial sequence was obtained by PCR on a human genomic library (p. 179 first column). However Malo does not teach the full-length sequence of SEQ ID NO:3, or nucleic acids encoding the full-length sequence.

Current Protocols Chapter 6 excerpts teaches the artisan of ordinary skill how to screen a DNA library to obtain clones. The specific techniques and protocols necessary for the

experiments are detailed, and troubleshooting tips are presented. Chapter 6.1 teaches the artisan of ordinary skill how to plate libraries and transfer them to filters; Chapter 6.3 teaches how to hybridize a DNA probe to the filters, and Chapter 6.5 provides guidance in isolating the appropriate clone. Note that each of the individual articles was originally published between 1989 and 1996, as indicated by the dates on the face page of each chapter. Thus the reference describes techniques to screen libraries and pull out a full-length clone which were well–known prior to the effective filing date of this invention. However Current Protocols does not teach either sodium channels or screening assays.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to screen a human DNA library in order to obtain a full-length clone encoding SCN1A, thereby arriving at the invention of claim 31, with a reasonable expectation of success. The motivation to do so would be to find inhibitors of human sodium channels, instead of rat sodium channels used by Noda. This motivation comes directly from the references themselves; note that Malo teaches that human tissues express SCN1A-encoding nucleic acid, and teaches that such nucleic acids can be obtained by screening libraries. The artisan of ordinary skill would have a reasonable expectation of success in obtaining full-length nucleic acid encoding human SCN1A (i.e., encoding the protein of SEQ ID NO:3), given that Noda provides the full-length rat sequence and Malo provides a partial human sequence. Either of these could be used as a probe in screening a library, such as the commercially available libraries used by Malo, or by making cDNA libraries from human neural tissue as described by Wood (p. 23 lines 5 – 11). Note that the Current Protocols chapters provide guidance to the artisan of ordinary skill in library-screening procedures, and Wood indicates that such procedures are suitable for purifying nucleic acids encoding human sodium channels. Further Wood indicates that these types of nucleic acids can be used in screening assays. Following the guidance set forth in these references, the artisan of ordinary skill would arrive at the invention of claims 14, 23, and 31, as human SCN1A is in fact the protein of SEQ ID NO:3. Isolation of the human, as opposed to the rat, SCN1A-encoding nucleic acid would not have been the result of innovation but rather of common sense. While none of the references explicitly teaches the nucleic acid sequence of SEQ ID NO:1, or a nucleic acid sequence encoding SEQ ID NO:3, following the guidance set forth in the references cited above one of ordinary skill in the art would obtain these products. Nucleic acid products can either be synthesized *de novo* or can be obtained by probing a library (see Wood, p. 5 line 18 – p. 6 line 13, as well as Example 1 from p. 17 line 30 – p. 22 line 22).

Conclusion

7. Claims 14, 17, 20, 23, and 31 are rejected.

8. Claims 30 and 32 – 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker, Ph.D./
Patent Examiner, Art Unit 1649
June 17, 2008